June 16, 2001

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FDA
Dockets Management Branch
5630 Fishers Lane
Room 1061 HFA-305
Rockville, MD 20852

Docket #01P-0259

Dear FDA:

I am a member of the IBS Self Help Group (www.ibsgroup.org) and wish to share with you my own personal experience with IBS. I think the impact of IBS on individuals is trivialized by the medical establishment and by groups such as Public Citizen. You should know that for some of us, IBS presents serious quality of life issues.

I first noticed symptoms of IBS after parasitic poisoning from a trip to Mexico. About five years later, I had a bad case of food poisoning and my IBS symptoms increased significantly. I have IBS type C (constipation predominant).

Last year, I lost my marriage of 20 years due in large part to my husband's inability to deal with my illness. I also went through two operations related to problems with constipation (and almost died from one of them). I lost three months of work and finally lost my job (got notice on my cell phone enroute to the Emergency Room at Yale New Haven for my second operation). Now I'm losing my home of 18 years as I can't work due to the IBS symptoms. Nor can I socialize or leave my home for any length of time.

The only relief I have had from the IBS has been the tegaserod I received in a clinical drug trial (now almost 3 years ago!). Novartis has applied for "compassionate use" of Zelnorm for me, but that has not been approved yet.

I just wanted to let you know that some people really do suffer tremendously as a result of their IBS symptoms. I'm not one to complain, but after 8 years of working to get my Ph.D. from Columbia University, it's frustrating that can no longer work as a professional in my field or even get a menial job. I was rejected for a job counting money at Sears!

Thank you for taking the time to hear my story.

Regards,

Gail S. Robinson, Ph.D.

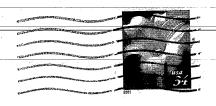
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